Please cancel claims 2,3 and 4, without prejudice.

Please amend the claims in the following manner:

1. (Once Amended) A polypeptide consisting of an amino acid sequence from Ala at position 14 to Gly at position 226 of SEQ ID NO:2 and having the biological property of gankyrin.

5. (Once Amended) A purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO:1 and that has the biological properties of gankyrin, wherein said stringent conditions are defined as washing said hybridized DNA at 50°C, with 2xSSC and 0.1% SDS.

Please add the following new claims:

35. A purified polypeptide that is encoded by a DNA capable of hybridizing under stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO:1 and that has the biological properties of gankyrin, wherein said stringent conditions are defined as washing said hybridized DNA at 65°C, with 0.1xSSC and 0.1% SDS.

REMARKS

After canceling claims 2-4, amending claims 1 and 5 and adding new claim 35, claims 1, 5, 16, 17 and 35 are now pending. All of the amendments to the claims are fully supported throughout the specification and therefore do not introduce new matter. For example, the stringent condition added in claim 5 is defined on page 12, lines 1-2; and the stringent conditions contained in new claim 35 are found on page 12, lines 4 –5. Additional support for new claim 35 is found throughout the specification, but specifically on page 51, lines 3-6. Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

The Examiner's Rejections Under 35 U.S.C. § 112 are Moot

In the September 13, 2001 Office Action (Paper No. 11), the Examiner rejected claim 5 under 35 U.S.C. § 112, second paragraph, as being indefinite, because the phrase "stringent condition" is indefinite. The Examiner is thanked for suggesting an amendment to the claims which would obviate this rejection. Claim 5 has been amended accordingly.

The Examiner also rejected claims 1-5 and 15-16 [*sic*, 16-17] under 35 U.S.C. § 112, first paragraph, because "[t]he specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims." (Paper No. 11, page 3).

Applicant respectfully disagrees with the Examiner's assessment of the specification in relation to the currently pending claims. Specifically, the rejection of claims 2-4, based on lack of enablement, is now moot in light of the cancellation of these claims. Additionally, the Examiner acknowledges that the specification is enabling for a polypeptide comprising the amino acid sequence from Ala at position 14 to Gly at position 226 (*see* Paper No. 11, page 3, first full paragraph, first sentence), which is the subject matter of claim 1. It also appears that the Examiner's rejection, based on lack of enablement, is focused on "modified polypeptides" and not necessarily on the polypeptide of SEQ ID NO: 1 (claim 1) or its complement (claim 5).

In making the rejection, the Examiner asserts that "it would require undue experimentation for one skilled in the art to practice the invention as claimed." (Paper No. 11, page 5). However, nothing more than routine screening would be required to practice the invention as currently claimed. And as the Federal Circuit espoused in *In re Wands*, "[e]nablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. 'The key word is 'undue,' not 'experimentation.'" *In re Wands* 858 F.2d 731,736-737 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d at 504).

Two of the factors listed in *In re Wands*, as well as in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) which may be considered in determining whether a specification is enabling are the state of the prior art, and the relative skill of those in the art. Making and using fusion proteins (claim 17), as well

as signal-added proteins (claim 16), are procedures well-known in the art, and thus the only support necessary to guide the skilled artisan in making and using fusion proteins and signal-added proteins containing the polypeptide of claim 1 would be a disclosure that outlines how to screen such polypeptides for gankyrin biological activity, which the current specification adequately supplies. Indeed, the Examiner acknowledges that "the disclosure exemplifies gankyrin biological activity in example 4." (Paper No. 11, page 4). Thus, according to the Examiner, the specification would provide one skilled in the art with guidance as to how to identify a polypeptide with gankyrin biological activity. Accordingly, the specification, combined with the high level of skill in the art, and the advanced state of the art regarding fusion proteins and signal-added proteins fully enable the claimed invention.

The Examiner's Rejection of Claims 16-17 Under 35 U.S.C. § 103 is Moot

In the September 13th Office Action, the Examiner rejected claims 15-16 [*sic*, 16-17] under 35 U.S.C. § 103(a) as being unpatentable over Zhang, Jamsa and Kato. Applicant respectfully traverses this rejection.

To establish a case of *prima facie* obviousness, the Examiner must meet three criteria. First the Examiner must show that the references upon which he or she relied teach every limitation of the currently claimed invention, *In re Royka,*490 F.2d 981, 985 (C.C.P.A. 1974). Second, the Examiner must show that there is some suggestion or motivation in the references themselves, or within the knowledge of one of ordinary skill in the art, to combine the references to arrive at the claimed invention. Lastly, the Examiner must show that there is a reasonable expectation of success in combining these references, and that this expectation of success is found in the references as well. *See In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicant asserts that the Examiner has not cited any art that meets these criteria, and thus has not fulfilled the burden of proving that the claims are obvious over the prior art.

First, none of the references, alone or in combination with each other, teach the polypeptide as is now claimed in amended claim 1. Specifically, Kato does not teach that a polypeptide starting with alanine at position 14 of SEQ ID NO: 2, exhibits gankyrin biological activity. Additionally, there is no objective motivation to combine the cited references, either found in the references themselves, or

within the knowledge of one of ordinary skill. Specifically, one of ordinary skill would not read Kato, Zhang, and/or Jamsa, or any combination thereof, and produce a fusion protein containing a shortened version of the full length gankyrin polypeptide.

Finally, even if motivation were to exist to produce the claimed invention, there would be no reasonable expectation of success found in the art. If the Examiner's assertion that "[p]rotein chemistry is probably one of the most unpredictable areas of biotechnology" was taken at face value, this would militate against any sort of reasonable expectation of success wherein a full length protein (Gankyrin, which consists of amino acids 1-226 of SEQ ID NO: 2) is reduced by the first thirteen amino acids, yet it still retained its biological activity.

Because the art cited by the Examiner fails to meet any of the criteria necessary to establish a *prima facie* case of obviousness, in view of the claims as currently drafted, the Examiner has not met her burden of establishing obviousness. Accordingly, reconsideration and withdrawal of the rejection based on 35 U.S.C. § 103 is earnestly solicited.

The Rejection of Claims 1, 3 and 5 Under 35 U.S.C. § 102(b) is Now Moot

In view of the amendments to claims 1 and 5, and the cancellation of claim 3, the Examiner's rejection of these claims under 35 U.S.C. § 102(b), as being anticipated by Kato, is now moot. Kato does not teach the polypeptide of claim 1 that possesses gankyrin biological activity. Withdrawal of this rejection is earnestly solicited.

CONCLUSION

Applicant has canceled claims 2-4, and amended claims 1 and 5, and added new claim 35. Accordingly, claims 1, 5, 16, 17 and 35 are currently pending in the application.

Rejections of claims 2-4, for any reason, are now moot in view of their cancellation. Additionally, the applicant has demonstrated that claims 1, 5, 16, 17 and 35 are enabled under the current specification. Furthermore, the applicant has demonstrated that the Examiner has not satisfied her burden of demonstrating that the currently pending claims are obvious in view of the art of record. Finally, in view of the amendments to the claims, the rejection under 102(b) should be withdrawn.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date March 13, 2002

By [signature] 48,574

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VERSION WITH MARKINGS TO SHOW CHANGES MADE UNDER 37 C.F.R. § 1.121(c)(ii)

1. A polypeptide [comprising] consisting of an amino acid sequence from Ala at position 14 to Gly at position 226 of SEQ ID NO: 2 and having the biological activity of gankyrin.

5. A purified polypeptide that is encoded by a DNA capable of hybridizing under [a] stringent conditions to a DNA having the nucleotide sequence as set forth in SEQ ID NO: 1 and that has the biological activity of gankyrin, wherein said stringent conditions are defined as washing said hybridized DNA at 50°C, with 2xSSC and 0.1% SDS.